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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/804,560

03/18/2004

Tami Harel

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

12/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/804,560	Applicant(s) HAREL ET AL.	
	Examiner MICHAEL KAHRELIN	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-55, 79-85, 87 and 101-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-55, 79-85, 87 and 101-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/25/2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 52, 53, 54, 82, 104, 105, and 106 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. In regards to claim 52, "every period of time" is vague because no "period of time" has been set forth.

5. In regards to claim 53, "in cases of doubt" is vague because it is unclear how an apparatus can have "doubt." If the apparatus is not the "doubting" element, it is unclear who or what has the "doubt." Further, "overstimulate" is vague because there is no basis of comparison for what constitutes a normal level of stimulation.

6. In regards to claim 54, "relatively" is unclear because there is no basis of comparison/relation.

Art Unit: 3762

7. In regards to claim 82, "programmed with a knowledge of" is vague because it is unclear whether this limitation pertains to the person programming the device, or whether the device has some sort of programmed data relating to insulin therapy.
8. In regards to claim 104, "said given period" is lacking antecedent basis.
9. In regards to claim 105, "said electric field" is lacking antecedent basis.
10. In regards to claim 106, it is unclear whether the claim recites an additional electrode, or further limits the "implantable electrode" of claim 52.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims are rejected under 35 U.S.C. 102(b) as being anticipated by Wernicke et al. (US 5,231,988, hereinafter "Wernicke").
13. In regards to claim 52, Wernicke discloses an apparatus for blood glucose control (abstract) comprising an implantable electrode (abstract) and circuitry for electrifying the electrode for a period of time at a frequency of 1-15 Hz (Tables I and II).
14. In regards to claim 53, the device is a closed-loop system (col. 7, lines 30-67) that over-stimulates (over no stimulation at all) in cases of doubt (that the blood glucose is at a normal level).
15. In regards to claim 54, the circuitry is semi-open loop where a relatively long stimulation series is applied without feedback (col. 7, lines 42-46).

Art Unit: 3762

- 16.** In regards to claim 55, the system is an open loop system (col. 9, lines 51-55).
- 17.** In regards to claim 79, the circuitry generates an electric field that reduces glucose in a non-insulin manner (abstract; the electric field works in a "non-insulin manner" because it reduces glucose by nerve stimulation, and not by supplying insulin in any manner).
- 18.** In regards to claim 81, the circuitry reduces or prevents a substantial increase in insulin secretion (abstract).
- 19.** In regards to claim 82, the apparatus is programmed with a knowledge of a slow-acting chemical-based insulin therapy provided to a pancreas (col. 87, lines 3-16).
- 20.** In regards to claims 83-85, the apparatus further comprises an automatic glucose sensor (col. 7, lines 35-40).
- 21.** In regards to claims 87 and 106, Wernicke discloses attachment of the electrode at the stomach (col. 6, lines 1-3).
- 22.** In regards to claims 103 and 104, the circuitry electrifies the electrode at 5 Hz with a pulse width of less than 30ms (Table I).
- 23.** In regards to claim 107, the electrode is electrified in synchrony with the electrical activity of the stomach (blood glucose rises with the electrical activity of the stomach associated with digestion).
- 24.** In regards to claim 108, the apparatus reduces high blood glucose levels, but does not reduce normal blood glucose levels (col. 7, lines 30-68).

Claim Rejections - 35 USC § 103

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

26. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

27. Claims 80 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wernicke. Wernicke discloses the essential features of the claimed invention except for reducing glucagon secretion or not substantially inducing new bursts of islet activity in a pancreas. It is well known to compensate by reducing glucagon levels to provide the predictable results of modify blood glucose levels faster than by modifying insulin alone, and to reduce blood glucose by not substantially inducing new bursts of islet activity in a pancreas to provide the predictable results of lowering blood glucose when patients do not have functioning islets in their pancreas. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made

Art Unit: 3762

to modify Wernicke's invention by reducing glucagon levels to provide the predictable results of modifying blood glucose levels faster than by modifying insulin alone, and to reduce blood glucose by not substantially inducing new bursts of islet activity in a pancreas to provide the predictable results of lowering blood glucose when patients do not have functioning islets in their pancreas.

28. Claims 101 and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wernicke. Wernicke discloses the claimed invention but does not disclose expressly the 20% reduction in elevated blood glucose levels. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the device as taught by Wernicke with the claimed level of glucose reduction because applicant has not disclosed that this specific level provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the device as taught by Wernicke because both devices lower blood glucose levels by a user-desired amount. Therefore, it would have been an obvious matter of design choice to modify Wernicke's invention to obtain the invention as specified in the claims.

Response to Arguments

29. Applicant's arguments with respect to claims 52-55, 79-85, 87, and 101-108 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment.

Double Patenting

30. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

Art Unit: 3762

unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

31. Claims 52-55, 79-85, 87, and 101-108 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 10 of copending Application No. 10/526,708 and claim 10 of Application No. 10/10570,576 in view of Wernicke. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are more narrow in scope than (anticipate) the claims of the instant application, or obvious variants in view of Wernicke.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

32. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sun (cited previously) is one of many teachings of modifying

Art Unit: 3762

glucagon secretion, and Houben (cited previously) is a teaching of not substantially inducing new bursts of islet activity in the pancreas.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762

/Angela D Sykes/
Supervisory Patent Examiner, Art Unit 3762